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### REMARKS

As of the date of the present Office Action, Claims 2, 5, 7, 14, 29-34, 3 and 41 were pending. Applicants appreciate the Examiner's removal of his previous rejections. The remaining two rejections are discussed in the following order:

- 1) Claims 2, 5, 7 14, 29-34 and 39 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly not meeting the written description requirement and/or containing new matter; and
- 2) Claim 41 stands rejected under 35 U.S.C. §102(a) allegedly being anticipated by Estell (WO 99/53078).

#### **1) The Claims Meet the Written Description Requirement**

The Examiner has rejected Claims 2, 5, 7 14, 29-34 and 39 under 35 U.S.C. §112, first paragraph, as allegedly not meeting the written description requirement and/or containing new matter. In particular, the Examiner argues that Applicants cannot exclude what was not specifically recited. Applicants have amended independent Claim 2, to remove the recitation excluding streptokinase. In case the Examiner is considering re-citing Carr (WO 98/52976) as teaching the modification of a kinase, Applicants respectfully submit that streptokinase is NOT a kinase. Although Applicants previously amended Claim 2 to recite that the kinase is not streptokinase, Applicants' representative did not intend to admit that streptokinase is actually a kinase. Indeed, upon additional research, Applicants' representative determined that this characterization is incorrect, as "streptokinase" is merely the name of a protein produced by members of the genus *Streptococcus*; it is not a "kinase," nor even an enzyme. Applicants submit that any previous implication that streptokinase is a kinase was in error and was not intended to deceive.

As known in the art, a "kinase" is an enzyme that acts by phosphorylating proteins (See e.g., Lehninger, Principles of Biochemistry, Worth Publishers, Inc., New York, NY [1982], at page 974; attached hereto at Tab 1; and Sharp (ed), Penguin Dictionary of Chemistry, The 2<sup>nd</sup> ed., Penguin Books, London, England [1990], at page 230; attached hereto at Tab 2). Streptokinase is NOT a kinase, as its function is to activate plasminogen by binding to it. Thus, rather than phosphorylating a protein, streptokinase binds to one (See e.g., Master Drug List—Pharmacology 2001-2002, at page 10; this document is located at

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><http://www.virginiadocs.com/Master%20Drug%20List-%20Pharmacology%202001-2002.doc><; and is attached hereto at Tab 3). As indicated at Tab 3, streptokinase is "[n]ot a kinase or an enzyme, binds to plasminogen to form plasmin . . . ." Furthermore, as indicated on page 2 of the printout from a web publication by Lizbeth Hedstrom (attached hereto at Tab 4), "[s]treptokinase is a plasminogen activator . . . . Unlike typical plasminogen activators, streptokinase is not a protease (nor is it a 'kinase')."

Thus, as streptokinase, which is taught by the Carr reference is NOT a kinase, the Carr reference does NOT teach nor suggest the presently claimed kinase variant having reduced allergenicity. Therefore, Applicants respectfully submit that the Claims are allowable over the Carr reference previously cited by the Examiner; the Claims meet the written description requirement; and the Claims do not contain new matter. Applicants respectfully request that the Claims be passed to allowance.

## 2) Claim 41 is Not Anticipated

The Examiner has rejected Claim 41, under 35 U.S.C. §102(a), as allegedly being anticipated by Estell (WO 99/53078). Furthermore, the Examiner argues that the parent application (U.S. Patent Appln. Ser. No. 09/060,872) does not provide descriptive support for the *Markush* group in the present Claim. Applicants must respectfully disagree with the Examiner's arguments. Nonetheless, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments, Applicants have amended Claim 41, such that "protease" is not included in the *Markush* group. As the Examiner has focused his arguments on the discussion of modified proteases in the Estell WO publication, Applicants submit that deletion of "proteases" in Claim 41 is sufficient to remove this rejection, particularly since the Examiner previously repeatedly indicated that Claim 41 is allowable. As the Estell (WO 99/53078) does not anticipate pending Claim 41, Applicants respectfully request that this rejection be withdrawn and the Claim be passed to allowance.

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### CONCLUSION

All grounds of rejection and objection of the Office Action of May 7, 2003, having been addressed, reconsideration of the application is respectfully requested. Applicants respectfully submit that the pending claims are in condition for allowance and issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (650) 846-5838.

Respectfully submitted,

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